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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
11/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/597,954	ABUDOKIRIM ET AL.	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/2007 & 2/13/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-20 are pending in this application.

2. Applicant's election of group I in the reply filed on September 12, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 11, 2008.

4. Claims 1-16 are under prosecution.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is indefinite over the recitation of the phrase "(macro-pores)" in lines 2 and 5 because it is not clear whether a recitation within parenthesis further defines structural features.

8. Claim 4 is indefinite over the recitation of "micro pore size of 0" in line 3 because zero micro pore cannot further limit the micropore as required in claim 3.

9. Claims 2-16 are indefinite because they are dependent from claim 1.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tennikova et al (J. High Resol. Chromatogr., 2000, 23, 27-38).

Regarding claim 1, Tennikova et al teaches an apparatus for separating and purifying nucleic acids comprising an integral monolith structure (i.e., monolithic continuous structures), wherein through-pores (macro-pores) continuously extending from one end of the monolith structure to the other end and corresponding to the sizes of nucleic acids are provided and configured so that nucleic acids corresponding to the through-pores (macro-pores) can be retained respectively by allowing a solution containing nucleic acids to be separated to pass there through (Fig. 4, right panel, Fig. 7, and Abstract, pg. 29, column 2, paragraph 3, pg. 32, column 2, paragraph 2).

Regarding claim 2, Tennikova et al teaches that the monolith structure employs an inorganic material (pg. 33, section 4.1) or a hybrid material containing an organic material and an inorganic material (Fig. 3b and Fig. 10, legend).

Regarding claim 3 and 7, Tennikova et al teaches that the porous body of the monolith structure has micro pores (i.e., small globules) in the macro pores (Fig, 3b and pg. 29, column 1, paragraph 1).

Regarding claims 4, 8 and 9, Tennikova et al teaches porous body of the monolith structure has through pores (macro pores) of sizes less than 5 um (Fig. 3b), which is within the range of 1 to 100 um as claimed. It is also noted that the claim recitation of micro pores of sizes from zero to 100 nm indicates that micro pores are not part of the claimed monolith structure when the size of the pore is zero nm. Therefore, teachings of Tennikova et al of monolith structure comprising macro pores meet the limitation of the claim.

Regarding claim 5 and 10-12, Tennikova et al teaches disc formed by monolith structure and further teaches disc is placed in a column tube to form a monolith solid phase column (Fig. 2, pg. 28, column 1, paragraph 2, column 2, paragraph 3)

Regarding claims 6 and 13-16, Tennikova et al teaches disc formed by monolith structure (Fig. 2, pg. 28, column 1, paragraph 2) and further teaches monolith solid phase column formed by detachably attaching a base formed with the monolith structure to a cylindrical body having the top and the bottom opened (Fig. 2, See the CIM monolith disks and dedicated cartridge with open end and pg. 28, column 2, paragraph 2, lines 1-3).

12. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatch (USPN 6,238,565 issued May 29, 2001).

Regarding claim 1, Hatch teaches an apparatus for separating and purifying nucleic acids comprising an integral monolith structure (i.e., monolithic continuous structures), wherein through-pores (macro-pores) continuously extending from one end of the monolith structure to the other end and corresponding to the sizes of nucleic acids are provided and configured so that nucleic acids corresponding to the through-pores (macro-pores) can be retained respectively by allowing a solution containing nucleic acids to be separated to pass there through (column 8, lines 1-19).

Regarding claim 2, Hatch teaches that the monolith structure employs a hybrid material containing an organic material (column 7, lines 57-65) and an inorganic material (column 8, lines 40-54).

Regarding claim 3 and 7, Hatch teaches that the porous body of the monolith structure has micro pores (i.e., small globules) in the macro pores (column 8, lines 13-17).

Regarding claims 4, 8 and 9, Hatch teaches porous body of the monolith structure has through pores (macro pores) of sizes of about 10 nm to less than 5 um (column 8, lines 1-3), which is within the range of 1 to 100 um as claimed. It is also noted that the claim recitation of micro pores of sizes from zero to 100 nm indicates that micro pores are not part of the claimed monolith structure when the size of the pore is zero nm. Therefore, teachings of Hatch of monolith structure comprising macro pores meet the limitation of the claim.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1- 4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch (USPN 6,238,565 issued May 29, 2001) in view of Urthaler et al (USPGPUBNO. 2004/0002081 filed, Dec. 18, 2002).

Following rejection is applied to meet the limitation of the size of the micro pores is greater than zero nm but less than 100 nm.

Claim 4 is dependent from claim 3, which is dependent from claim 2, which is dependent from claim 1. Claim 9 is dependent from claim 2. Claim 8 is dependent from claim 1. Teachings of Hatch regarding claims 1-3 are described in this office action in section 12.

Regarding claims 4, 8 and 9, Hatch teaches that the porous body of the monolith structure has micro-pores (i.e., small globules) in the macro-pores (column 8, lines 13-17) and further teaches the sizes of macro-pores are about 1-5 microns (column 8, line 16), which is in the range of 1 to 100 microns as claimed. Hatch also teaches that the size of the micro-pores are about 1-2 microns (column 8, line 15), but is silent about the size of the micro-pores in the range of zero to 100 nm. However, size of the micro pores in monolithic structures were known in the art at the time of the claimed invention was made as taught by Urthaler et al.

Urthaler et al teaches a monolithic structure comprising macro and micro pores and further teaches the size of the micropore (i.e., mesopore) is about 13 nm, which is in the range of 0-100 nm as claimed (paragraph 0028). Urthaler also teaches that the monolith structures comprising micro pores of nanometer size pores have a higher flow rates and is better for transport and separation of macromolecules (paragraph 0028 and 0029).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the micro pore size of Hatch with micro pore of nanometer size pores of Urthaler et al with a reasonable expectation of success with the expected benefit of having monolith structures comprising micro pores of nanometer size pores, which have a higher flow rates and better for transport and separation of macromolecules as taught by Urthaler et al (paragraph 0028 and 0029).

16. Claims 1- 6 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch (USPN 6,238,565 issued May 29, 2001) in view of Tennikova et al (J. High Resol. Chromatogr., 2000, 23, 27-38).

Teachings of Hatch regarding claims 1-4 are described previously in this office action in section 12.

Regarding claims 5 and 10 -12, Hatch teaches solid phase column comprising monolith structure (column 9, lines 63-65) but are silent about disc formed with monolith structure.

Regarding claims 6 and 13-16, Hatch teaches a monolith solid phase column formed with the monolith structure to a cylindrical body having the top and the bottom opened (i.e., column with diameter and length, column 10, lines 17-19 and lines 27-28) but are silent about forming column by detachably attaching a base formed with monolith structure. It is noted that the structural requirements recited in said claims are cylindrical body having open at both ends (i.e., open column) and monolith disc. As described above Hatch teaches the open column.

However, disc formed with monolith structure was known in the art at the time of the claimed invention was made as taught by Tennikova et al.

Tennikova et al teaches disc formed by monolith structure (Fig. 2, pg. 28, column 1, paragraph 2) and further teaches monolith solid phase column formed by detachably attaching a base formed with the monolith structure to a cylindrical body having the top and the bottom opened (Fig. 2, See the CIM monolith disks and dedicated cartridge with open end and pg. 28, column 2, paragraph 2, lines 1-3). Tennikova et al also teaches

that monolithic discs are most reliable and cheap, allow separation of macromolecules very rapidly, and are far superior to the traditionally used slow columns (pg. 32, column 1, paragraph 1, pg 37, column 2, and paragraph 2).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the monolith solid phase column of Hatch with disc formed with monolith structure of Tennikova et al with a reasonable expectation of success with the expected benefit of having monolithic discs, which are most reliable and cheap, allow separation of macromolecules very rapidly, and are far superior to the traditionally used slow columns as taught by Tennikova et al (pg. 32, column 1, paragraph 1, pg 37, column 2, paragraph 2).

Conclusion

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634